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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/714,796	11/17/2003	Kenneth W. Dobie	HTS-0016US.P1	2946

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EXAMINER

MCGARRY, SEAN

ART UNIT PAPER NUMBER

1635

DATE MAILED: 04/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>		<b>Applicant(s)</b>	
	10/714,796		DOBIE ET AL.	
	<b>Examiner</b>		<b>Art Unit</b>	
	Sean R. McGarry		1635	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-8,13-19,23-28 and 44-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-8,13-19,23-28 and 44-68 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-8, 13-16, 23, 49-51, 59-61 and 65, drawn to an antisense oligonucleotide targeted to kinesin-like 1 encoding nucleic acid which comprises at least an 8 nucleobase portion of SEQ ID NO: 86, classified in class 536, subclass 24.5.
- II. Claims 1-8, 13-16, 23, 49-51, 59, 60, 62, and 66, drawn to an antisense oligonucleotide targeted to kinesin-like 1 encoding nucleic acid which comprises at least an 8 nucleobase portion of SEQ ID NO: 96, classified in class 536, subclass 24.5.
- III. Claims 1-8, 13-16, 23, 49-51, 59, 60, 63, and 67, drawn to an antisense oligonucleotide targeted to kinesin-like 1 encoding nucleic acid which comprises at least an 8 nucleobase portion of SEQ ID NO: 116, classified in class 536, subclass 24.5.
- IV. Claims 1-8, 13-16, 23, 49-51, 59, 60, 64, and 68, drawn to an antisense oligonucleotide targeted to kinesin-like 1 encoding nucleic acid which comprises at least an 8 nucleobase portion of SEQ ID NO: 122, classified in class 536, subclass 24.5.
- V. Claims 17-19, 24-28, 44-48, 52-58, drawn to a method of inhibiting the expression of kinesin-like 1 via an antisense oligonucleotide targeted to a kinesin-like 1 encoding nucleic acid which comprises at least an 8

nucleobase portion of SEQ ID NO: 86, classified in class 514, subclass 44.

- VI. Claim 17-19, 24-28, 44-48, 52-58, drawn to a method of inhibiting the expression of kinesin-like 1 via an antisense oligonucleotide targeted to a kinesin-like 1 encoding nucleic acid which comprises at least an 8 nucleobase portion of SEQ ID NO: 96, classified in class 514, subclass 44.
- VII. Claim 17-19, 24-28, 44-48, 52-58, drawn to a method of inhibiting the expression of kinesin-like 1 via an antisense oligonucleotide targeted to a kinesin-like 1 encoding nucleic acid which comprises at least an 8 nucleobase portion of SEQ ID NO: 116, classified in class 514, subclass 44.
- VIII. Claim 17-19, 24-28, 44-48, 52-58, drawn to a method of inhibiting the expression of kinesin-like 1 via an antisense oligonucleotide targeted to a kinesin-like 1 encoding nucleic acid which comprises at least an 8 nucleobase portion of SEQ ID NO: 1222, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-IV are directed to related antisense oligonucleotides targeted to kinesin-like 1 alpha. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together

or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the antisense oligonucleotides of each invention are required to have defined a sequence/structure. The different sequences required in each invention do not overlap. Each antisense has a different sequence that targets a different portion of a kinesin-like 1 alpha nucleic acid. Each antisense would have a different activity based on its sequence (see table 1 of the instant specification, for example).

Inventions V-VIII are directed to related methods that use antisense oligonucleotides to inhibit kinesin-like 1. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the antisense oligonucleotides used in each invention is required to have defined a sequence/structure. The different sequences required of the different antisense used in each invention do not overlap. Each antisense has a different sequence, which targets a different portion of a kinesin-like 1 alpha nucleic acid. Each antisense used in the instant methods would have a different activity based on its sequence (see table 1 of the instant specification, for example).

Inventions (I-IV) and (V-VIII) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

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different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the methods could be performed with an antisense oligonucleotide that does not have an eight nucleobase portion of SEQ ID NO: 86, 96, 116, or 122, for example. One might use a different compound to inhibit the expression of a kinesin-like 1 alpha such as a triplex forming oligonucleotide, for example..

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR

1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

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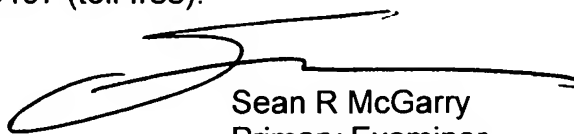
unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean R. McGarry whose telephone number is (571) 272-0761. The examiner can normally be reached on M-Th (6:00-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Sean R McGarry  
Primary Examiner  
Art Unit 1635